EXHIBIT C

GenBioPro

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April 9, 2023

The Honorable Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993-0002

Re: ANDA #A091178 (GenBioPro / Mifepristone)

Dear Commissioner Califf:

I am writing regarding GenBioPro's ("GBP") abbreviated new drug application ("ANDA") for mifepristone (No. 091178), GBP's March 1, 2023 Letter to FDA ("March 1 Letter"), and FDA's March 24, 2023 Letter from Center for Drug Evaluation and Research Director Patrizia Cavazzoni, MD ("March 24 Letter") responding to our March 1 Letter. On April 7, 2023, two separate federal district courts issued rulings relating to mifepristone and FDA's approval of GBP's ANDA. In view of these two rulings, the issues raised in our prior correspondence have taken on even greater and more pressing importance. GBP respectfully submits that those issues require FDA's immediate attention and action.

As explained in the March 1 Letter, GBP is dedicated to ensuring that people have access to evidence-based, essential medications and, to that end, GBP markets a generic version of Mifeprex® (mifepristone) 200 mg consistent with FDA's regulatory framework. In the March 1 Letter, we wrote to request confirmation that any withdrawal or suspension of the approval of GBP's ANDA for mifepristone—whether by court order or otherwise—would follow all applicable procedures afforded by law and regulation to GBP as the ANDA holder, and that FDA would permit GBP to continue marketing and selling mifepristone unless and until those procedures have been completed.

In the March 24 Letter, FDA declined to confirm that it would follow all applicable rules and procedures for any withdrawal or suspension of GBP's ANDA. Indicating the reason for its response, FDA referenced the litigation in *Alliance for Hippocratic Medicine v. FDA* ("*AHM*"), No. 2:22-CV-00223-Z (N.D. Tex.), in which the plaintiffs had argued that "'the Court, on its own accord, can order the FDA to withdraw or suspend the approval of the drug,' rather than 'order the FDA to begin a suspension or withdrawal' process under 21 U.S.C. § 355(e)." March 24 Letter (quoting Arg. Tr. at 145-46). The March 24 Letter then stated that FDA would "need to review the Court's opinion and order before determining what steps may be necessary to comply with it."

On April 7, the *AHM* court issued an order that dramatically increased the legal importance of the March 24 Letter. Mem. Op. and Order, *All. for Hippocratic Med.*, No. 2:22-CV-00223-Z (N.D. Tex. Apr. 7, 2023), ECF No. 137 ("*AHM* Order"). The *AHM* Order purported to "stay" the effective

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date of a number of FDA actions, including FDA's approval of GBP's ANDA for mifepristone, under 5 U.S.C. § 705. *Id.* at 65-67.

On the same day as the *AHM* Order, a federal court in Washington state issued a separate ruling enjoining FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy under 21 U.S.C. § 355-1 in" 17 states and the District of Columbia. *Washington v. FDA*, No. 1:23-CV-3026-TOR (E.D. Wash. Apr. 7, 2023), ECF No. 80 ("*Washington* Order") at 30.

In light of these two conflicting orders—and particularly the *AHM* Order, which purports to alter the validity of FDA's approval of GBP's ANDA—GBP respectfully requests the following:

First, FDA should immediately commit that it will not withdraw, suspend, or otherwise take action that would impair GBP's ANDA approval and associated rights. In particular, but without limitation, FDA should not make any changes to GBP's registration or product listing with the agency, and it should not remove GBP's ANDA from the Orange Book. The *AHM* Order does not order FDA to take any of these actions, and FDA should not interpret the *AHM* Order to require them. Disrupting the status quo—and upending more than 22 years of mifepristone access—is premature at this stage and would have devastating public health consequences.

As detailed in the March 1 Letter, GBP's ANDA was approved by FDA on April 11, 2019, following almost a decade of efforts by GBP to bring the first and only generic version of Mifeprex (mifepristone) 200mg tablet to market. As you know, mifepristone 200 mg tablet is the first drug in a two-drug regimen approved by FDA for medication abortion. FDA's approval of mifepristone reflected its judgment that this medication is safe and effective and was based on a robust review of vast amounts of data and hundreds of medical studies over more than two decades, including data submitted by GBP to support approval of its ANDA. FDA's decisions regarding mifepristone have twice been found to be legally and factually valid by the U.S. Government Accountability Office. *See* U.S. Gov't Accountability Off., *Approval and Oversight of the Drug Mifeprex* (Aug. 2008); U.S. Gov't Accountability Off., *Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* (Mar. 2018).

Congress has recognized the public health benefits of mifepristone as well. As the March 1 Letter explained, in enacting the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, Congress specified that 16 drugs that FDA had approved previously with "elements to assure safe use" would be deemed by statute to have an effective Risk Evaluation and Mitigation Strategy (REMS) in place. As to the set of drugs, including mifepristone, that have a REMS with elements to assure safe use, Congress mandated that any elements provide "safe access" for patients to the drug, and not be "unduly burdensome on patient access to the drug." 21 U.S.C. § 355-1(f). FDA thus regulates mifepristone under this congressional mandate, which requires safe access for patients. FDA most recently revised the REMS for mifepristone on January 3, 2023, after an extensive review of updated research and data. The *Washington* Order commands FDA to maintain the REMS as currently in effect with respect to the 17 plaintiff states and the District of Columbia in that lawsuit. *Washington* Order at 30.

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The *AHM* Order, in contrast, purports to order a "stay" of, among other things, the 2000 Mifeprex approval and the 2019 approval of GBP's ANDA. *AHM* Order at 67. But in recognition of the public and private reliance on FDA's approval of drugs as safe and effective, Congress vested the authority to stay or suspend an approved drug application *exclusively* in the Secretary of Health and Human Services; Congress also restricted that authority to be used only in extraordinary circumstances. *See* 21 U.S.C. § 355(e). Specifically, under the Federal Food, Drug, and Cosmetic Act ("FDCA"), if the Secretary "finds that there is an imminent hazard to the public health, he may suspend the approval of [an NDA] immediately." 21 U.S.C. § 355(e).[1]

Contrary to the *AHM* Order's suggestion that a federal court is permitted to "second-guess FDA's decision-making," *AHM* Order at 57, Congress expressly directed that the Secretary's suspension authority "shall not be delegated" to anyone, 21 U.S.C. § 355(e). Rather, as the Supreme Court has explained, "an NDA remains effective unless it is suspended" pursuant to the authority vested exclusively in the Secretary by 21 U.S.C. § 355(e). *See Weinberger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609, 633 (1973). Moreover, in the extreme circumstances in which the Secretary finds an "imminent hazard" and orders the immediate suspension of an application approval, the approval holder is entitled to immediate procedural protections, including "prompt notice," and "an expedited hearing." 21 U.S.C. § 355(e); *see* 21 C.F.R. § 314.150(a)(1).

Secretary Becerra has made no "imminent hazard" finding with respect to mifepristone. Under Supreme Court precedent, therefore, all mifepristone approvals "remain[] effective." *See Weinberger*, 412 U.S. at 633.[2]

Second, FDA should immediately commit that, in the event the *AHM* Order is deemed to alter the validity of FDA's Mifeprex approval, FDA nonetheless will not withdraw, suspend, or otherwise take action that would impair GBP's ANDA approval and associated rights. As the *AHM* Order itself recognizes, "[i]f FDA withdraws the listed drug on which the ANDA-approved generic drug is based, the agency is *generally* required to withdraw the generic drug as well." *AHM* Order at 60 (emphasis added). Though it recognizes that rule as "general[]," the *AHM* Order ignores the actual criteria for any such withdrawal. *See id.* (declaring the court is "inclined to agree with Plaintiffs" based solely on analysis of the Mifeprex NDA without analyzing the generic drug withdrawal provisions at 21 U.S.C. § 355(j)). Those legal criteria do not apply here.

Specifically, FDA regulations provide that, if the reference drug in GBP's ANDA is required to be withdrawn for reasons other than *FDA's determination* that the reference drug is unsafe or ineffective for use under the conditions set forth in its application, then its withdrawal has no impact on GBP's ANDA for mifepristone. *See* 21 U.S.C § 355(j)(6); 21 C.F.R. § 314.151. Here, FDA has made no determination that the reference drug is not safe or effective. Instead, a court has purported to "stay" the effective date of approval of the approved reference drug. While the

[1] The *AHM* Order appears to equate a judicially ordered "stay" with the Secretary's suspension authority, noting that the court considered ordering FDA to "suspend the chemical abortion approval" as an alternative to its "stay." *See AHM* Order at 67.

[2] The FDCA also allows for the withdrawal of an approved drug application under specified circumstances. 21 U.S.C. § 355(e). Withdrawal requires a finding by FDA that one of the relevant statutory criteria has been met. *Id.* It also requires extensive procedures before a withdrawal may occur. *Id.*; *see* 21 C.F.R. §§ 314.150, 314.200, 314.530.

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effect of that "stay" on Mifeprex is also without legal basis, at a minimum, the Mifeprex "stay" can have no legal effect on approval of GBP's ANDA under section 355(j) and its implementing regulations. Moreover, GBP is not a party to the *AHM* litigation and, as the Supreme Court has held, "[i]t is a violation of due process for a judgment to be binding on a litigant who was not a party or a privy and therefore has never had an opportunity to be heard." *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 327 n.7 (1979).

Third, regardless of any other action FDA takes in response to the *AHM* Order, FDA should immediately issue a non-enforcement order declaring that it will not, under any circumstances, take any enforcement action against GBP or its distributors, customers, and partners based on the *AHM* Order's purported "stay" of GBP's ANDA. This includes, but is not limited to, any enforcement action pursuant to 21 U.S.C. §§ 355(a), 331(d), 333(a), and 334(a). FDA is authorized to issue such a non-enforcement order based on its wide discretion to develop enforcement priorities and to articulate the exercise of that discretion to regulated entities. *See Heckler v. Chaney*, 470 U.S. 821, 832 (1985).

A non-enforcement order is particularly appropriate here because there is a direct conflict between two federal courts. *See Nat'l Env't Dev. Assoc.'s Clean Air Project v. EPA*, 891 F.3d 1041, 1045 (D.C. Cir. 2018) (upholding agency's adoption of "permissible and sensible solutions to issues emanating from intercircuit conflicts and agency nonacquiescence"). The *AHM* Order "stays the effective date" of FDA's approval of Mifeprex and GBP's ANDA. *AHM* Order at 67. At the same time, the *Washington* Order prohibits FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative" REMS in 17 states. *Washington* Order at 30. These two rulings cannot be reconciled, and distributors, doctors, patients, and manufacturers all require guidance.

Fourth, FDA should issue an interim final rule with immediate effect, declaring that FDA's approval of GBP's ANDA shall remain effective pending public comments and any further judicial review of the *AHM* Order. Such a rule is authorized by the FDCA, 21 U.S.C. § 371(a) ("The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary"), and the Administrative Procedure Act, 5 U.S.C. § 553(b)(B) (notice-and-comment procedures not required when they are "impracticable, unnecessary, or contrary to the public interest").[3] With an interim rule in effect, FDA can then accept public comments to address, among other things, how it should reconcile the conflicts between the *Washington* Order and the *AHM* Order, including but not limited to the relevant geographic scope of the *AHM* Order.

Even aside from the conflicting judicial orders, good cause exists to issue an interim rule here. *See* 5 U.S.C. § 553(b). The potential nationwide unavailability of mifepristone due to court action presents a grave threat to public health. FDA should accordingly issue an interim final rule to affirm all mifepristone approvals and open a comment period to gather public input.

[3] FDA commonly issues interim final rules with subsequent comment periods, including for issues surrounding drugs. *See, e.g., Applications for Food and Drug Administration Approval To Market a New Drug; Revision of Postmarketing Reporting Requirements—Discontinuance*, 76 Fed. Reg. 78,530 (Dec. 19, 2011).

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Thank you for your consideration of this matter of pressing public importance. In light of the exigency of this matter, we respectfully request FDA's response as immediately as practicable. If you or your staff have questions, please do not hesitate to reach out.

Sincerely,

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